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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/374,704 08/12/99 BAIRD

E 238/298

EXAMINER

HM12/0328

LYON & LYON LLP
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SUITE 4700
LOS ANGELES CA 90017

EPES, I

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

10
03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/374,704

Applicant(s)

BAIRD ET AL.

Examiner

Janet L Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20,21,23 and 24 is/are allowed.
- 6) ☒ Claim(s) 1-19, 25-26 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6,8
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequence Information

2. The paper copy and computer readable form of the sequence listing, received 10/22/1999, is technically sound and has been entered into the STIC Sequence database.

Priority

3. The disclosure of application 08/607,078, filed 2/26/1996 does not provide support for the polyamides of the instant invention wherein said polyamides comprise a positive patch consisting of a rigid group, wherein said rigid group comprises a first and a second amino acid, and further wherein the first amino acid is selected from arginine, proline, lysine, and hydroxyproline, and said second amino acid is selected from proline, glycine, serine, threonine, leucine, isoleucine, valine, alanine, and hydroxyproline. For this reason the priority date for claims 1-26 is 4/21/1997.

4. Claims 1, 5, 9, and 25-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bruce et al., and is repeated for the reasons set forth in the prior Official Action.

5. Applicant's arguments filed 1-04-01 have been fully considered but they are not persuasive. Applicants traverse these rejections on the grounds that the compounds of the instant invention comprise amongst other elements, a positive patch consisting of a rigid group, and that the compounds of Bruce et al. do not disclose a positive patch

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according to the instant invention. However, the specification as filed and the instant claims states that the positive patch consists of a rigid group, wherein said rigid group comprises a first and a second amino acid. The first amino acid is selected from arginine, proline, lysine, and hydroxyproline, and said second amino acid is selected from proline, glycine, serine, threonine, leucine, isoleucine, valine, alanine, and hydroxyproline. The compounds disclosed by Bruice et al. comprise at least two proline residues and an arginine type moiety bearing a positively charged guanidinium residue.

Claim Rejections - 35 USC § 102

6. Claims 1, 4-5, 9-12, 14, 16, 18 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Swalley et al., Parks et al. or Trauger et al.

Swalley et al. (Figure 2, structure 2, page 8200), Parks et al. (Figure 2, page 6154) or Trauger et al. (Figure 3, page 6162) disclose polyamides comprising N-methylimidazole and N-methylpyrrole, and N,N-dimethylaminopropylamide moieties, and one or more non-alpha amino acids such as γ -aminobutyric acid or β -alanine, and further bearing a terminal positively charged group. Additionally each reference disclose polyamides bearing hairpin linkages derived from γ -aminobutyric acid (see abstract of each reference).

Swalley et al., Parks et al. and Trauger et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2-8, 9-19 and 25-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Swalley et al., Parks et al. and Trauger et al. in view of Feng et al.

Claim 2-3 reads on the polyamides of claim 1 further comprising a first and second amino acid, wherein said first amino acid is selected from arginine, proline, lysine, and hydroxyproline, and said second amino acid is selected from proline, glycine, serine, threonine, leucine, isoleucine, valine, alanine, and hydroxyproline.

Claims 6-7 read on a polyamide of claim 1 wherein said positively charged groups is arginine, lysine, or histidine.

The polyamide compounds of Swalley et al., Parks et al. and Trauger et al. comprise amino acid moieties bearing N-methylimidazole and N-methylpyrrole, and N,N-dimethylaminopropyl-amide moieties (as described above). The instant claims read on a polyamide comprising proline and arginine. It would have been obvious to incorporate Arg-Pro-Arg into the polyamide compounds of those disclosed in the cited references since the compounds of the prior art comprise amino acid moieties that are chemically and functionally similar to proline, namely N-methylpyrrole, or arginine,

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positively charged N,N dimethylamino-propylamide, or histidine, namely N-methylimidazole.

However, the cited references do not teach polyamides wherein the positive patch comprises the amino acid sequence Arg-Pro-Arg.

Feng et al. disclose a polyamide compound which specifically interacts with the minor groove of DNA utilizing the sequence Gly₁₃₉-Arg₁₄₀-Pro₁₄₁-Arg₁₄₂ at the carboxyl terminal domain, and binds to the major groove involving a helix-turn-helix α -helix motif. The binding of the polyamide to DNA results in a site-specific inversion reaction at the site of binding. This specific inversion reaction can be used to activate or inactivate gene expression.

Polyamide compounds comprising one or more amino acids selected from N-methylpyrrole, and N-methylimidazole, wherein one or more of said amino acids are not α -amino acids for the reasons given above. It would have been obvious to modify these polyamides with a sequence comprising Arg-Proline-Arg since polyamide compounds comprising these sequence are known to bind DNA with high affinity in a sequence specific manner, this modification would ^{have} broaden the sequence repertoire of these polyamide compounds for DNA recognition. The ability to enlarge the sequence repertoire of a polyamide would ^{have} ^{ed} help to develop "a universal approach for the recognition of any desired DNA sequence by strictly chemical methods (Swalley et al., p. 8200, para. 5)."

Therefore, the invention as a whole is *prima facie* obvious over Swalley et al., Parks et al. and Trauger et al. in view of Feng et al.

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Claim Objections

9. Claim 22 is objected to because of the following informalities: Claim 22, line 15, recites an unrecognizable character immediately before the word "alanine." It is likely that Applicants intended the claim to recite " β -alanine." Appropriate correction is required.

10. Claims 2-19 recite "[a] polyamide of claim 1," this phrase is vague and indefinite since claims 2-19 are dependent claims. The use of the indefinite article "A" to begin dependent claims renders the scope of these claims uncertain.

Allowable Subject Matter

Claims 20-24 are allowable over the prior art of record or any combination thereof. The Swalley et al., Parks et al. and Trauger et al. and Feng et al. references only teach linear polyamide molecules, however, the instant claims read on 4 or more polyamide molecules linked in tandem by a hairpin bridge derived from γ -aminobutyric acid.



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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

jle
March 26, 2001



JOHN L. LeGUYADER
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